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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,356	05/09/2001	Martin A. Cheever	014058-009811US	1297
20350	7590	10/27/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/854,356

**Applicant(s)**

CHEEVER ET AL.

**Examiner**

MISOOK YU, Ph.D.

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004 and 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 113-144 is/are pending in the application.
- 4a) Of the above claim(s) 126-144 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 113, 114 and 116-125 is/are rejected.
- 7) ☒ Claim(s) 115 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/09/01</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> .                                   |

### **DETAILED ACTION**

Applicant's amendments filed on 06/21/04, and 08/10/04 are acknowledged.

Claims 113, 123, 127, and 138 are amended. Claims 113-144 are pending.

### ***Election/Restrictions***

This application contains claims 126-144 drawn to an invention nonelected with traverse in Paper filed on 05/06/2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 126-144 remain withdrawn for reason of record, drawn to a non-elected invention.

Claims 113-125 are under consideration.

This Office action contains new grounds of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification, Maintained***

The disclosure remain objected to because of an embedded hyperlink and/or other form of browser-executable code at page 10 for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, Withdrawn***

The rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

The rejection of claims 113-125 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

***Claim Rejections - 35 USC § 102, Withdrawn***

The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Disis et al (IDS, 1996, The Journal of Immunology, vol. 156, pages 3151-8) is withdrawn because the amended claims are no longer anticipated by the art.

***Claim Rejections - 35 USC § 103, Withdrawn***

The rejection of claims 117, 119, 120, 122-125 under 35 U.S.C. 103(a) as being unpatentable over Disis et al (IDS, 1996, The Journal of Immunology, vol. 156, pages 3151-8) as applied to claims 113, 114, 118, and 121 above, and further in view of applicant's admission at page 51, line 19 to line 31 of 52 is also withdrawn because Disis et al., is no longer an art for the amended claims.

***The Following Are New Grounds of Rejection***

***Claim Objections***

Claim 116 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim depends upon the base claim 113, drawn to method of using the fusion protein, which comprises at

least 90% identity to SEQ ID NO:6. However, SEQ ID NO:7 is not at least 90% identity to SEQ ID NO:6, but about 78% identity to SEQ ID NO:6. Note Exhibit A (the sequence alignment)

***Claim Rejections - 35 USC § 112***

Claims 113, 114, and 116-125 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This new matter rejection is made due to the newly added limitation "at least 90% identity to SEQ ID NO:6" in base claim 113.

Applicant states that the percent identity has support at page 9, lines 27-32. However, the claimed invention is not drawn to polynucleotide with 90% identity but the claimed invention is drawn to method of administering to a worm blooded animal a composition comprising a fusion protein at least 90% identity to SEQ ID NO:6. The Office is unable to locate the support that the claimed invention is a method of administering to a worm blooded animal a composition comprising a fusion protein at least 90% identity to SEQ ID NO:6 in the specification as originally filed. Applicant is kindly requested to point out the support in the specification as originally filed.

***Allowable Subject Matter***

Claim 115 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642





Matches 712; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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OY 1 MELAAALCRWGLLALLPFGAASVQVCTGTDMLRLPASPETHLMDLRHLVGGCCVQGNL 60
DB 1 MELAAALCRWGLLALLPFGAASVQVCTGTDMLRLPASPETHLMDLRHLVGGCCVQGNL 60
OY 61 ELTYLPTNASLSTFLQDQVGVVLAHNOVQVPLQRLRIYRGTLQFEDNYALAVDNG 120
DB 61 ELTYLPTNASLSTFLQDQVGVVLAHNOVQVPLQRLRIYRGTLQFEDNYALAVDNG 120
OY 121 DPLNNTPVYTGASPGGLREIQRLSLTEILKGVLLIQRNPQLCYOFTILMKDIFKNNOLA 180
DB 121 DPLNNTPVYTGASPGGLREIQRLSLTEILKGVLLIQRNPQLCYOFTILMKDIFKNNOLA 180
OY 181 LTLIDTRSRACHPCSPMCKSGSRMGESSEDCOSLTRVCAAGGACRCKGRLPTCCHEOC 240
DB 181 LTLIDTRSRACHPCSPMCKSGSRMGESSEDCOSLTRVCAAGGACRCKGRLPTCCHEOC 240
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DB 241 AAGCTGPKHSDCLACLFHNSGICELHCPALVTYNTDFFESMPNDEGRYTFGASCTYACP 300
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DB 301 YNLTSTDVGSCTLVCPHLNQEYTAEDGTORCEKSKPCARVCYGLGMEHLREVAATYSAN 360
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DB 361 IOEPAGCKKIFGSLAFPLPESFDGDPASNTAPLQPEOLQVFTLEITGYLYTISAMPDLSL 420
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DB 421 DLSVFQNLQVIRGLIHLNGAVSLTLOGLSIMLGLRSRLRELSGLALIHNTILCFVHTY 480
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DB 601 PSQVKPDLSTYMPIMKFPDEBEGACQPCPINCTHSCVDLDKGCAPAEORASPLTJSQNEIDL 660
OY 661 ASPLDSTFYRSLLEDDDMGDLVDAEYLVPOQGFECBPAPAGAGVNHNRH 712
DB 661 ASPLDSTFYRSLLEDDDMGDLVDAEYLVPOQGFECBPAPAGAGVNHNRH 712

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## RESULT 11

US-09-854-356-3

Sequence 3, Application US/09854356

Patent No. US2002017367A1

GENERAL INFORMATION:

APPLICANT: Cheever, Martin A.

APPLICANT: Cheysen, Dirk

APPLICANT: Corixa Corporation

APPLICANT: SmithKline Beecham Biologicals S. A.

TITLE OF INVENTION: HER-2/neu Fusion Proteins

FILE REFERENCE: 014058-009810PC

CURRENT FILING DATE: 2001-05-09

PRIOR APPLICATION NUMBER: US 09/493,480

PRIOR FILING DATE: 2000-01-28

PRIOR APPLICATION NUMBER: US 60/117,976

PRIOR FILING DATE: 1999-01-29

NUMBER OF SEQ ID NOS: 26

SOFTWARE: PatentIn Ver. 2.1

SEQ ID NO 3

LENGTH: 653

TYPE: PRT

ORGANISM: Homo sapiens  
 FEATURE:  
 OTHER INFORMATION: extracellular domain (ECD) of human HER-2/neu  
 US-09-854-356-3

Query Match 71.4%; Score 3628; DB 9; Length 653;  
 Best Local Similarity 100.0%; Pred. No. 5, 1e-202;  
 Matches 653; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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OY 1 MELAAALCRWGLLALLPFGAASVQVCTGTDMLRLPASPETHLMDLRHLVGGCCVQGNL 60
DB 1 MELAAALCRWGLLALLPFGAASVQVCTGTDMLRLPASPETHLMDLRHLVGGCCVQGNL 60
OY 61 ELTYLPTNASLSTFLQDQVGVVLAHNOVQVPLQRLRIYRGTLQFEDNYALAVDNG 120
DB 61 ELTYLPTNASLSTFLQDQVGVVLAHNOVQVPLQRLRIYRGTLQFEDNYALAVDNG 120
OY 121 DPLNNTPVYTGASPGGLREIQRLSLTEILKGVLLIQRNPQLCYOFTILMKDIFKNNOLA 180
DB 121 DPLNNTPVYTGASPGGLREIQRLSLTEILKGVLLIQRNPQLCYOFTILMKDIFKNNOLA 180
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DB 181 LTLIDTRSRACHPCSPMCKSGSRMGESSEDCOSLTRVCAAGGACRCKGRLPTCCHEOC 240
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DB 241 AAGCTGPKHSDCLACLFHNSGICELHCPALVTYNTDFFESMPNDEGRYTFGASCTYACP 300
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DB 301 YNLTSTDVGSCTLVCPHLNQEYTAEDGTORCEKSKPCARVCYGLGMEHLREVAATYSAN 360
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DB 361 IOEPAGCKKIFGSLAFPLPESFDGDPASNTAPLQPEOLQVFTLEITGYLYTISAMPDLSL 420
OY 421 DLSVFQNLQVIRGLIHLNGAVSLTLOGLSIMLGLRSRLRELSGLALIHNTILCFVHTY 480
DB 421 DLSVFQNLQVIRGLIHLNGAVSLTLOGLSIMLGLRSRLRELSGLALIHNTILCFVHTY 480
OY 481 PMQLFRNPHQALHTANRPEDCEVGEGLACQOLCARHCHGPGPTQCVNCSQFLRGQEC 540
DB 481 PMQLFRNPHQALHTANRPEDCEVGEGLACQOLCARHCHGPGPTQCVNCSQFLRGQEC 540
OY 541 VECRCVLOGLPREYVNAHCLPCHEPCOPONGSVTCFGEADQCVACAHKDDPPFCVANC 600
DB 541 VECRCVLOGLPREYVNAHCLPCHEPCOPONGSVTCFGEADQCVACAHKDDPPFCVANC 600
OY 601 PSQVKPDLSTYMPIMKFPDEBEGACQPCPINCTHSCVDLDKGCAPAEORASPLTJSQNEIDL 660
DB 601 PSQVKPDLSTYMPIMKFPDEBEGACQPCPINCTHSCVDLDKGCAPAEORASPLTJSQNEIDL 660

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## RESULT 12

US-09-921-161-1

Sequence 1, Application US/09921161

Patent No. US2002009062A1

GENERAL INFORMATION:

APPLICANT: Ralph, Peter

APPLICANT: SmithKline Beecham Biologicals S. A.

TITLE OF INVENTION: ANALYTICAL METHOD

FILE REFERENCE: GENENT.066A

CURRENT FILING DATE: 2001-08-01

PRIOR APPLICATION NUMBER: 60/225,433

PRIOR FILING DATE: 2000-08-15

NUMBER OF SEQ ID NOS: 1

SOFTWARE: FastSeq for Windows Version 4.0

SEQ ID NO 1

LENGTH: 645

TYPE: PRT

ORGANISM: Homo sapiens

US-09-921-161-1